

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**

THE CITY OF HUNTINGTON,

Plaintiff,

v.

AMERISOURCEBERGEN DRUG
CORPORATION, *et al.*

Defendants.

Civil Action No. 3:17-01362

CABELL COUNTY COMMISSION,

Plaintiff,

v.

AMERISOURCEBERGEN DRUG
CORPORATION, *et al.*

Defendants.

Civil Action No. 3:17-01665

**DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION *IN LIMINE*
TO PRECLUDE ANY REFERENCE TO THE DEA APPROVING
OR ENDORSING A PARTICULAR DEFENDANT'S SOM PROGRAM**

I. INTRODUCTION

Plaintiffs’ Motion to exclude evidence of and preclude references to DEA’s approval or endorsement of any Defendant’s suspicious order monitoring program—filed two weeks into trial and after Plaintiffs themselves have introduced evidence on this topic—is inexplicable and unfounded. An issue in this trial, *according to Plaintiffs*, is whether Defendants caused a public nuisance by unreasonably shipping too many prescription opioid pills to customers located in Cabell County and the City of Huntington. And, *according to Plaintiffs*, Defendants’ compliance with the Controlled Substance Act (CSA)—and what Defendants knew about DEA’s expectations for distributors under its implementing regulations—is relevant to their claim. Thus, based on Plaintiffs’ own view of this case, evidence of what DEA has said to Defendants about their suspicious order monitoring programs is relevant.

Plaintiffs’ own actions during the first two weeks of trial have not just opened the door to evidence on these topics, but ushered it into the record. Plaintiffs solicited testimony and proffered documentary evidence that, they say, shows what DEA communicated to Defendants about DEA’s views on what the law requires. Yet Plaintiffs now want to preclude Defendants from presenting evidence of the contrary explanations and endorsements that DEA provided over time. Plaintiffs’ effort to have the evidence run only one way is legally unfounded.

Plaintiffs’ examination of Chris Zimmerman, ABDC’s Senior Vice President of Corporate Security and Regulatory Affairs, illustrates the “heads-I-win, tails-you-lose” nature of Plaintiffs’ Motion. Plaintiffs questioned Mr. Zimmerman at length about what DEA has said and done. In fact, *Plaintiffs* asked the very questions that first elicited testimony about DEA’s approval of ABDC’s SOM program in 1998.¹ Plaintiffs did not object or move to strike this testimony when

¹ Trial Tr. (May 12, 2021) at 219:7-25, 224:21-225:3; Trial Tr. (May 13, 2021) at 55:24-56:10.

it came in. Yet they now want to undo this testimony—and block future testimony like it—because they do not like the answers their own questioning elicited. Plaintiffs’ Motion is improper and unfounded, and it should be denied.

II. ARGUMENT

Plaintiffs claim that Defendants violated the CSA by failing to design and operate adequate Suspicious Order Monitoring (SOM) programs. While Defendants disagree that this is a legally viable basis for a public nuisance tort claim, or that it is factually accurate, Plaintiffs have chosen to base their case on Defendants’ compliance with the CSA and its implementing regulations. DEA is the regulatory body responsible for enforcing the CSA. Plaintiffs themselves have put into evidence various communications from DEA to Defendants as a reflection of Defendants’ supposed obligations under the CSA and regulations. Defendants are therefore entitled to put on responsive evidence showing that DEA was aware of and/or approved of the manner in which Defendants operated their SOM programs over time—including and especially approval or endorsement of a SOM program.

Plaintiffs try to obscure the issue here by speaking in the abstract. Their Motion speaks generally of hypothetical, unidentified statements made by anonymous DEA employees. But the trial record already provides a specific example of this type of evidence: in 1998, DEA formally approved ABDC’s new SOM program—and did so in writing. Trial Tr. (May 13, 2021) at 180:13-184:17. This evidence, which the Court has already admitted, bears directly on DEA’s views of, and statements about, ABDC’s SOM program. This evidence is pertinent to all Defendants, because DEA was aware that ABDC was shipping and then reporting suspicious orders under the 1998 program it approved, *id.* at 186:4-21—which undercuts Plaintiffs’ baseless assertion that DEA purported to require distributors to block suspicious orders prior to 2007.

A. Plaintiffs Have Opened the Door by Repeatedly Soliciting Evidence of DEA’s Communications with Defendants.

Plaintiffs’ Motion should be denied because Plaintiffs have opened the door by repeatedly soliciting evidence regarding DEA’s communications with Defendants regarding their SOM programs and purported obligations during trial. For example, *Plaintiffs* introduced into evidence the “Dear Registrant” letters sent to all distributors in 2006 and 2007, through which DEA informally provided additional information regarding DEA’s new expectations for distributors. *See* Trial Tr. (May 12, 2021) at 211:12-212:12 (Plaintiffs introducing Exhibit P-32 and describing one letter as “a communication from the United States Drug Enforcement Agency... related to the duties to maintain effective control and for the purposes of monitoring suspicious orders”). Notably, one of these letters explicitly discussed prior approval of SOM programs, writing:

Past communications with DEA, whether implicit or explicit, that could be construed as *approval of a particular system* for reporting suspicious orders, should no longer be taken to mean that DEA approves a specific system.

Ex. P-00032_0003 (Dec. 27, 2007 Dear Registrant Letter) (emphasis added).² It is absurd to suggest that a letter revoking a prior approval is admissible evidence, while the original letter providing the approval is not. It likewise makes no sense to suggest that these “Dear Registrant” letters—addressed to no distributor in particular and sent to the industry at large—are admissible, while letters that DEA sent to a specific Defendant about that Defendant’s SOM Program are not.

In addition, *Plaintiffs* have solicited extensive testimony from witnesses on this exact topic. For example, Plaintiffs questioned ABDC witness Chris Zimmerman about the 1998 DEA approval:

² Plaintiffs cite this letter as proof that DEA did not approve Defendants’ programs. Mot. at 3; *see also id.* Ex. A. While the evidence shows that Plaintiffs’ contention is unfounded, the salient point for purposes of this Opposition is that Plaintiffs’ introduction into evidence of this letter (and other documents cited in Plaintiffs’ Motion) opened the door to evidence of DEA’s approval of Defendants’ programs.

Q. Do you have anything in writing where the DEA has ever said to AmerisourceBergen that it approves using a multiplier for purposes of monitoring suspicious orders of controlled substances?

A. We have a letter approving the program that we developed with the three multiplier. I also have a letter -- I think I've seen a letter from the DEA office asking us to raise the multiplier to six.

See Trial Tr. (May 13, 2021) at 55:24-56:6; *see also id.* at 38:13-39:1. And **Plaintiffs** questioned Mr. Zimmerman on related topics, including: what information DEA has provided to Defendants (Trial Tr. (May 12, 2021) at 175:10-12, 197:16-198:15, 202:4-203:7, 218:15-219:8); whether Defendants and DEA agree about matters of regulatory interpretation (*id.* at 189:21-190:6, 191:4-18); and whether Defendants were on “notice” of DEA’s positions (*id.* at 219:2-8, 221:8-222:5).

In short, Plaintiffs have not only opened the door on this topic, they have actively solicited this evidence. Having now obtained it, they cannot move to excise from the trial one side of the story simply because they do not like it.

B. Evidence of DEA Approval or Endorsement of Any Defendant’s SOM Program Is Relevant and Admissible.

Even setting aside Plaintiffs’ door-opening, evidence like the 1998 approval letter may be relevant and admissible for several reasons.

First, Plaintiffs maintain that a key question in this public nuisance action is whether Defendants’ conduct was reasonable. *See, e.g.,* Proposed Pretrial Order at 15 (Dkt. 1089) (Plaintiffs’ Summary) (“A public nuisance is an act or condition ***that unreasonably interferes with a right common to the general public.***” (emphasis in original)); Trial Tr. (May 3, 2021) at 57:3-5 (Plaintiffs’ Opening Statement) (“This case is about the ***unreasonable*** interference. It’s about the ***unreasonable*** interference with the public health, public safety, and the public peace of this community.” (emphasis added)). DEA’s awareness of Defendants’ SOM programs and its communications with Defendants about those programs is relevant to whether Defendants’

conduct in fashioning and maintaining those programs during the applicable time periods was *reasonable*.

Second, Plaintiffs have repeatedly insisted that Defendants’ “knowledge and intent” is relevant to their cause of action. *See, e.g.*, Dkt. 1338. Plaintiffs have also emphasized the relevance of notice. *See, e.g.*, Dkt. 1355-9 at 1-2. Yet the evidence Plaintiffs want to bar speaks to knowledge, intent, and notice from DEA. Statements by DEA approving or endorsing a SOM program may be relevant to show Defendants’ *state of mind* regarding their regulatory compliance. They also may be relevant to show the *notice* DEA provided to Defendants of its views. The fact that Plaintiffs do not like what this evidence says provides no reason to exclude it.

Judge Polster denied this same motion in the MDL Track 1 trial, stating: “And I will say at the outset, I’m going to have a very wide strike zone when it comes to the parties introducing evidence about what the federal government, DEA, FDA, did or did not do.” *See In Re: Nat’l Prescription Opiate Litig.* (MDL No. 2804), Oct. 15, 2019 Hearing Tr. at 5:6-10; *see also id.* at 11:14-16 (“If the defendants have documents from the DEA relevant to one of their programs, they can introduce it.”). In his written order memorializing his *in limine* rulings, Judge Polster stated, “[T]his evidence is relevant to determining whether Defendants acted knowingly and intentionally.” *Nunc Pro Tunc* Evidentiary Order at 22-23 (MDL No. 2804, Dkt. 3058).³

Plaintiffs now argue that this type of evidence “is inadmissible because it purports to state a conclusion of law—that a Defendants’ SOM program was CSA-compliant.” Motion at 1. This

³ Both the motion filed in the MDL and the motion filed here speculate that Defendants “may try to argue that this evidence is relevant to an equitable estoppel defense,” and then spend several pages attempting to rebut that argument. Motion at 4-7; *see also* Pls.’ Omnibus Mot. *in Limine* at 12-17 (MDL No. 2804, Dkt. 2652). This is a red herring: DEA is not a party, and Defendants do not seek to estop it or any other agency of the federal government. The law of equitable estoppel as it applies to government enforcement actions is irrelevant here.

is incorrect. It is a *fact* that DEA sent a letter to ABDC in 1998 with the subject line: “Approve suspicious order monitoring system.” Trial Tr. (May 13, 2021) at 183:8-17. The fact of the letter-approval supports the factual conclusions that, among other things, (i) DEA believed ABDC’s 1998 program was compliant with the CSA, and (ii) ABDC acted reasonably in believing it was compliant. The approval letter is not a legal conclusion—it is relevant evidence. *See* Fed. R. Evid. 401 (“Evidence is relevant if ... it has any tendency to make a fact more or less probable than it would be without the evidence....”).⁴

Plaintiffs may disagree about what conclusion should be reached based on evidence like the 1998 approval letter, but that goes to weight, not admissibility. Plaintiffs are free to advance their own view of this evidence through the normal means, including cross-examination and presentation of other evidence.⁵

C. Plaintiffs Have Waived Any Objection to This Evidence.

As explained above, Plaintiffs’ Motion should be denied on the merits. It also should be denied because Plaintiffs have waived any objection to this evidence more than once.

The Federal Rules of Evidence require that a party raise timely objections to evidence, or such objections are deemed waived. *See* Fed. R. Evid. 103(a)(1)A) (requiring a party claiming error in a ruling to admit evidence only if the party “timely objects or moves to strike); *see also*,

⁴ This evidence is not a legal conclusion. But it also bears emphasis that Plaintiffs’ argument that this evidence constitutes an inadmissible legal conclusion is yet another example of Plaintiffs trying to have it both ways. During their questioning of Mr. Zimmerman, Plaintiffs repeatedly asked Mr. Zimmerman about legal issues, including: the language of the CSA (Trial Tr. (May 13, 2021) at 155:9-156:6); the purpose of the CSA (*id.* at 156:16-158:15, 181:22-182:13); what duties the CSA imposes on distributors (*id.* at 160:17-163:17, 164:17-165:18); and awareness of case law regarding the CSA (*id.* at 167:2-3, 198:16-199:16). Defendants do not concede that this type of questioning is appropriate or admissible. The critical point for purposes of this Motion, however, is that *Plaintiffs* have already actively solicited this testimony and cannot now selectively curtail only those parts they do not like.

⁵ Plaintiffs may of course raise objections to any particular evidence in the normal course. Defendants do not seek a ruling that an entire category of evidence is per se admissible; instead they dispute Plaintiffs’ argument that an entire category of evidence is per se inadmissible.

e.g., Carnegie Mellon Univ. v. Marvell Tech. Grp., Ltd., No. CV 09-290, 2012 WL 12894752, at *2 (W.D. Pa. Dec. 18, 2012) (“It is well-settled that a party may waive an objection by failing to timely raise the objection at trial.”).

Plaintiffs have long known that Defendants would introduce this exact evidence at trial. In October 2020, Defendants discussed the 1998 DEA approval letter in their summary judgment briefing, *see* Dkt. 1079 at 17, and included the approval letter on their exhibit list.⁶ ABDC then discussed the approval letter in opening statements—***without objection***. *See* Trial Tr. (May 3, 2021) at 106:21-107:20 (ABDC Opening Statement) (discussing and quoting the 1998 approval letter). Plaintiffs then offered evidence and elicited testimony from a witness about the approval—***again without objection***. *See e.g.* Trial Tr. (May 12, 2021) at 219:7-25, 224:21-225:3; Trial Tr. (May 13, 2021) at 55:24-56:10. And ABDC introduced into evidence DEA’s letter approving ABDC’s program contained in ABDC’s files—***yet again without objection***. Trial Tr. (May 13, 2021) at 181:23-182:10. Plaintiffs’ failure to lodge a timely objection to the introduction of this evidence therefore constitutes a waiver.

III. CONCLUSION

Evidence of DEA approval or endorsements of any Defendants’ SOM programs is relevant and admissible. The Court should deny Plaintiffs’ Motion.

Dated: May 18, 2021

⁶ For example, the version of the approval letter produced by DEA was included as Exhibit DEF-WV-01921 on Defendants’ October 2, 2020 Exhibit List, with the description: “July 23, 1998 Letter from Patricia M. Good to Bergen Brunswig re Approve Suspicious Order Monitoring System.” Correspondence related to DEA’s approval produced by ABDC was also included as exhibits DEF-WV-00006 and DEF-WV-00015.

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on May 18, 2021, the forgoing *Defendants' Opposition To Plaintiffs' Motion in Limine to Preclude Any Reference to the DEA Approving or Endorsing a Particular Defendant's SOM Program* was sent to Counsel for the Plaintiffs and Defendants using the Court's CM/ECF system, which will send notification of such filing to all counsel of record.

/s/ Gretchen M. Callas

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